

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE-

: Marie-Christine MISSANA et al

Group Art Unit: 3738

Serial No

: 09/980,120

(U.S. National Phase of PCT/FR00/01457)

Examiner: D. J. Isabella

Filed

: November 30, 2001

(I.A. Filed May 29, 2000)

For

: BREAST PROSTHESIS

APPEAL BRIEF

Commissioner For Patents PO Box 1450 Alexandria, Virginia 23313-1450

TECHNOLOGY CENTER R3700

Sir:

This appeal is from the Examiner's final rejection of April 2, 2003. Appellant filed a Notice of Appeal on October 2, 2003, along with a request for a two-month extension of time, and is filing this Appeal Brief within the two-month due date of December 2, 2003.

A. REAL PARTY IN INTEREST

The real party in interest for the invention is the inventive entity, i.e., inventors Marie-Christine MISSANA and Arnaud ROCHEBILIERE, as evidenced by the declaration filed with the instant US national stage application on November 30, 2001.

B. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences which would directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

C. STATUS OF CLAIMS

Claims 24, 25, 27, 32-36, 41, 42, 48-63, 74 and 75 stand finally rejected under 35 USC 112, first paragraph, as lacking support in the original specification.

Claims 22-75 stand finally rejected under 35 USC 112, second paragraph, as being indefinite.

Claim 22-75 stand finally rejected under 35 USC 102(b) as being anticipated by, or in the alternative, under 35 USC 103(a) as obvious over GB 2 136 692 (incorrectly identified in the Final Rejection as GB2146692) to SCHWEIKHART.

D. STATUS OF AMENDMENTS

A response to the Final Official Action was filed on August 4, 2003. However, the Examiner has failed to issue an Advisory Action and has not indicated whether the response has been considered. A copy of the above-noted response was also sent by facsimile transmission to the Examiner on August 18, 2003. No amendment, other than the aforementioned response, has been filed following the final rejection.

E. SUMMARY OF INVENTION

By way of non-limiting example, the invention is directed to a breast prosthesis.

Figure 1 shows a transverse cross-section of a thorax in a mediastinal window passing by the fourth dorsal vertebra. The figure is schematically shown from a scannographic illustration. The figure illustrates a spine 10, two breasts 11 and 12, a mediastinum 13, lung fields 14 and 15, and a costal plane 16. It can be seen that the two breasts "spread" naturally on the thoracic plane 16 wherein each breast assumes a convex shape. The side arrows represent the inner and outer limits of the projection of the two areolar glands on the thorax. See lines 24-29 of page 5 of the instant specification.

Figure 2 shows, along the same cross-section as in Figure 1, some of the drawbacks of one type of (comparative) prosthesis that is currently commercially available. As can be see from the figure, the prostheses 21 and 22 have respective planar posterior surfaces 23 and 24 which do not follow the curvature of the thorax. In addition, they create, in the inner zones 25 and 26 for connection with the thorax, an almost 90° angle with the thorax. This is almost the same situation in the outer connection zones 27 and 28, wherein the external appearance of the prosthesis is unaesthetic. Moreover, such prostheses 21 and 22 are susceptible of moving in the pocket where they are implanted. This has the effect of increasing the unaesthetic effect and the discomfort for the person. See page 5, line 30 to page 6, line 4 of page 6 of the instant specification.

Figure 3 shows the prostheses 31, 32 according to a preferred embodiment of the invention. As can be seen in Fig. 3, the prostheses 31, 32 more closely resemble the breasts of Figure 1. They have a posterior surface 33, 34 assuming the convexity of the thorax as closely as possible. They also have connections in inner zones 35, 36 and in outer zones 37, 38 which have a gentle slope. The prostheses 31, 32 also have a volume that is better distributed and closer to the thoracic cage. As a result, they are much less susceptible of moving. In contrast to the prostheses 21, 22 of the prior art, the prostheses 31, 32 shown in Fig. 3 are made side-specific, are not interchangeable with each other, and are asymmetrical in the same way as natural breasts. See lines 5-12 of page 6 of the instant specification.

Figures 4-6 show the geometry of the right prosthesis 31 in detail. See line 13 of page 6 of the instant specification.

Figure 4 shows a front view of the right prosthesis 31 of Figure 3. It is understood from this representation, as well as those of Figs. 5 and 6, that one can derive the details of the left breast 32 based upon the details of the right breast 31 because the left breast 32 is the mirror image construction in volume of the right prosthesis 31. The representation shown in Figs. 4-6 are shown with a scale of 1:1. See lines 14-17 of page 6 of the instant specification.

In Fig. 4, point E is shown is the front pole of the prosthesis and corresponds to the nipple of the natural breast. Point C designates the inner edge (i.e., the edge that is oriented

toward the other prosthesis 32 in the implantation position). Points B and D designate the upper and lower front edges, respectively. Point A designates the front outer edge (as opposed to "inner"). Point A' designates the rear outer edge and point D' designates the rear lower edge. The prosthesis 31 has a volume of about 480 cm³. See lines 18-23 of page 6 of the instant specification.

The dimensions of the distances between these various points, measured in the plane P2, are as follows:

AA' = 1 cm (length of the outer overlap)

A'C = 14 cm (base of the prosthesis)

AC = 15 cm (total width of the prosthesis)

BD = 12 cm (total height of the prosthesis)

DD' = 2 mm

A'E = EC = 7 cm

AE = 8 cm

BE = 7 cm

ED = 5 cm

See lines 24-34 of page 6 of the instant specification.

As can be seen in Fig. 4, the prosthesis 31 does not have any symmetry in relation to the plane P1 passing by B, D, and E, and perpendicular to the plane P2. The distance EC is

notably shorter than the distance AE, and the volumes of the upper outer part 40 and lower outer part 42 are larger than those of the volumes of the upper inner part 41 and lower inner part 43. The hatched area 44 corresponds to an overlap of the anterior surface in relation to the surface developed by the posterior surface, which translates into the distance separating the points A and A' (see also Fig. 5). This overlap is most substantial in the vicinity of the points A and A' and extends up into the inner lower part 43 (i.e., the distance between D and D' is not negligible). The prosthesis 31 also has an asymmetry between the volumes of the lower outer part 42 and upper outer part 40, on the one hand, and between the volumes of the lower inner part 43 and upper inner part 41, on the other hand. This translates into the difference between the distances BE and ED. In the present case, the ratio r (BE/ED) is 1.4. This ratio can be generally selected preferably between 1.1 and 2, and especially between 1.3 and 1.5. See lines 1-13 of page 7 of the instant specification.

Figure 5 shows a horizontal cross-sectional view of Fig. 4. According to this cross-section, point F is the pole of the anterior surface 52 and G the pole of the posterior surface 51. Reference designation G' represents the projection of G in the plane P4 which is a plane that is perpendicular to the plane of the cross-section, and which passes by points k and C. It must be noted that the axes BD of Fig. 4 and FG of this Figure are perpendicular to one another, but with an offcentering of about 1 cm, i.e., they do not intersect with one another. See lines 14-19 of page 7 of the instant specification.

The distances between these various points are:

GG' = 1.3 cm

FG = 5 cm (front projection of the prosthesis)

kG' = 6 cm

GC = 8 cm

See lines 20-24 of page 7 of the instant specification.

With regard to Fig. 5, one can see that the posterior surface 51 has a uniform concavity extending between the points k and C. This concavity can be quantified by the distance GG' (which is greater than 1 cm) and by the angles α and α ' formed by the planes tangent to the posterior surface 51 (at points k and C) with the plane P4. The two angles α and α ' on the outer and inner side are substantially identical. These angles can be about 25°. They can also be in the range of between 20° and 30°, or these angles could also be other that these values. It can be noted that point G' is not in the middle of kC. Instead, there is an A'G/G'C ratio of about 0.75. This ratio can also, for example, be in the range of between 0.5 and 1. The hatched area 53 corresponds to the outer overlap designated by the reference numeral 44 in Fig. 4. This area 53 of the prosthesis provides the natural effect of an outwardly projecting breast. See lines 25-34 of page 7 of the instant specification.

Fig. 5 also shows the gentle slope connection mentioned previously. Namely, there is a gentle connection between the inner edge C of the prosthesis and the thorax. The plane

P8 is tangent to the posterior surface 51 at point C and forms, together with the plane P7 which is tangent to the anterior surface at same point C, a small angle β . This angle β is much less than 90° and can be on the order of 40°. See lines 1-5 of page 8 of the instant specification.

Figure 5 also shows that the outer overlap 53 also translates into an angle ϕ of about 115° at point k between the plane P5 passing by k and tangent to the anterior surface 52 and the plane P6 also passing by k and tangent to the posterior surface 51 of the prosthesis 31. See lines 6-8 of page 8 of the instant specification.

Figure 6 shows a side view of the prosthesis 31. The point I is the pole of the anterior surface 52 along the plane of Fig. 6. The point H is the pole of the posterior surface 51 along the plane of Fig. 6. The point H' is the perpendicular projection of point H on a vertical plane P9 passing by point B and perpendicular to the plane of Fig. 6. The distances between these various points are as follows:

HH' = 3.5 mm

HI = 5 cm (front projection of the prosthesis)

HD = 5 cm

H'B = 7 cm

DD' = 2 mm

See lines 9-18 of page 8 of the instant specification.

As can be seen in Fig. 6, the posterior surface 51 has a second concavity in the plane of Fig. 6. This concavity can be quantified by the distance HH' which is greater than 1 mm, and by the angle χ formed by the plane P10 tangent to the posterior surface 51 at point B with the plane P9. The situation is the same on the other side near point D' with regard to angle χ' , wherein the concavity extends from B up to D'. Here, the angles χ and χ' are each about 7°, and can, for example, be in the range of between 4° and 15°. See lines 19-23 of page 8 of the instant specification.

Figure 6 also illustrates a second gentle slope connection on the upper zone of the prosthesis. Namely, at point B, the angle δ formed by the plane P10 explained previously and the plane P11 tangent to the anterior surface 52 to point B is small, i.e., much less than 90° or 60°, and can be about 38.5°. See lines 24-27 of page 8 of the instant specification.

The distance HI is an important characteristic of the prosthesis because it makes it possible to define the front projection of the prosthesis 31. In this specific example, the distance HI is 5 centimeters. However, this distance HI can be selected more generally in a range of 3-7 centimeters. See lines 28-30 of page 8 of the instant specification.

In conclusion, this non-limiting example of prosthesis 31 is the one that combines all of the characteristics of the invention for even closer approximation to the natural breast than was previously known. Prostheses of various volumes and similarities can result from the invention. On the other hand, the invention is not limited to prostheses that do not utilize all

of the benefits of the prosthesis of the invention, i.e., they need not have all of the following features to be side specific:

adaptation to the convexity of the thorax by a concave posterior surface, and/or at least one "gentle slope connection", and/or an asymmetry in relation to a vertical plane passing by the nipple, and/or an outer "overlap"...).

See page 8, line 31 to page 9, line 4 of the instant specification.

The invention encompasses other embodiments and/or features which are not described herein. However, all the claimed features have been explained with sufficient clarity to enable the reader to understand the invention.

F. ISSUES ON APPEAL

- (1) Whether the Drawings Are Improperly Objected to Under 37 C.F.R. section 1.121(f), as Lacking Support in the Original Disclosure.
- (2) Whether Claims 24, 25, 27, 32-36, 41, 42, 48-63, 74 and 75 Are Improperly

 Rejected Under 35 U.S.C. section 112, First Paragraph, as Not Supported

 by the Original Specification.
- (3) Whether Claims 22-75 Are Improperly Rejected Under 35 U.S.C. section

 112, Second Paragraph, as Being Indefinite.

(4) Whether Claims 22-75 Are Improperly Rejected Under 35 U.S.C. section

102(b) as Being Anticipated By, Or in the Alternative, Under 35 U.S.C.

section 103(a) as Being Obvious Over GB 2 136 692 to SCHWEIKHART.

G. GROUPING OF CLAIMS

The following groups of claims are considered to stand or fall together, but only for the purpose of this appeal: claims 23, 48-50, 58 and 63-69 stand or fall with claim 22; claim 27 stands or falls with claim 25; claims 29-31 stand or fall with claim 28; claims 33 stands or falls with claim 32; claims 39 and 40 stand or fall with claim 38; claims 44 and 45 stand or fall with claim 43; claims 46 and 47 stand or fall with claim 41. The remaining claims do not stand or fall with any other claims.

H. ARGUMENT

(1) The Objection to the Drawings Under 37 C.F.R. section 1.121(f), as

Lacking Support in the Original Disclosure is in Error, the Examiner's

Decision to Object to the Drawings Should be Reversed, and the

Application Should be Remanded to the Examiner.

Reversal of the objection to the drawings under 37 CFR 1.121(f), as lacking support in the original disclosure is requested.

As a preliminary matter, Appellant is unsure whether the Board has jurisdiction regarding the instant objection. Accordingly, Appellant is concurrently filing a petition for withdrawal of this objection. Should it be determined that this objection is within the jurisdiction of the Board, Appellant respectfully requests resolution of this matter on Appeal. On the other hand, if the Board lacks jurisdiction in this matter, Appellant is requesting that this matter be held in abeyance until final resolution on petition.

The Examiner asserts that the drawings filed May 9, 2002 lack support in the original disclosure. In particular, the Examiner explained that there is no support in the original disclosure for the character lines χ ' and α '.

Appellant respectfully disagrees and submits that the drawings are fully supported by the original disclosure and are in full compliance with current USPTO rules.

As explained in the Interview of July 31, 2003, and as was apparently acknowledged by the Examiner, Fig. 6 and page 7, lines 26-30 of the original specification provides clear support for complementary angles χ and χ '. Moreover, page 8, lines 19-24 provides clear support for complementary angles α and α '.

With regard to angles α and α ', Appellant notes that page 7, lines 26-30 of the original disclosure states with reference to Fig. 5, "Therefore, one easily sees that the posterior surface 51 has a uniform concavity extending between the points k and C. This concavity can be quantified by the distance GG' which is greater than 1 cm, and by the **angles** α formed

by the planes tangent to the posterior surface 51, at points k and C, with the plane P4. Here, the two angles on the outer and inner side are substantially identical (about 25°, which can be comprised between 20° and 30°), but it could be otherwise." (Emphasis Added).

Moreover, Appellant has previously amended the specification consistent with these changes to the drawings. Thus, the paragraph between lines 25-34 of page 7 has been amended as follows:

"Therefore, one can easily [sees] see that the posterior surface 51 has a uniform concavity extending between the points k and C. This concavity can be quantified by the distance GG[']' which is greater than 1 cm, and by the angles α and α ' formed by the planes tangent to the posterior surface 51, at points k and C, with the plane P4. Here, the two angles α and α ' on the outer and inner side are substantially identical (about 25°, which can be [comprised] in the range of between 20° and 30°), but it could also be otherwise. It can be noted that G[']' is not in the middle of kC. There is an A[']'G/G[']'C ratio of about 0.75 (for example [comprised] in the range of between 0.5 and 1). The hatched area 53 corresponds to the outer overlap designated by the reference numeral 44 in the previous Figure[; it]. This makes it possible to see more clearly that the prosthesis allows obtaining the natural effect of an outwardly projecting breast." See Appendix 7 of the Second Preliminary Amendment.

With regard to angles χ and χ ', Appellant notes that page 8, lines 19-23 of the original disclosure states with reference to Fig. 6, "The posterior surface 51 has a second concavity

in the plane of the Figure. This concavity can be quantified by the distance HH' which is greater than 1 mm, and by the angles χ formed by the plane tangent to the posterior surface 51 at point B with the plane P9. (The situation is the same at point D', the concavity extending from B up to D'). Here, the angle χ is about 7°, and can be comprised between 4° and 15°, for example." (Emphasis Added).

Moreover, Appellant has previously amended the specification consistent with these changes to the drawings. Thus, the paragraph between lines 19-23 of page 8 has been amended as follows:

"The posterior surface 51 has a second concavity in the plane of the Figure. This concavity can be quantified by the distance HH[']' which is greater than 1 mm, and by the [angles] angle χ formed by the plane P10 tangent to the posterior surface 51 at point B with the plane P9. (The situation is the same [at] on the other side near point [D'] D' with regard to angle χ' , the concavity extending from B up to D[']'). Here, the [angle] angles χ and χ' [is] are each about 7°, and can be [comprised] in the range of between 4° and 15°, for example." See Appendix 8 of the Second Preliminary Amendment.

Thus, Appellant submits that the noted drawing changes find clear and full support in the original disclosure. For reasons given above, reversal of the Examiner's decision to finally object to the drawings as lacking support in the original disclosure is requested.

The Rejection of Claims 24, 25, 27, 32-36, 41, 42, 48-63, 74 and 75 Under

35 U.S.C. section 112, First Paragraph, as Containing Subject Matter

Which is Not Supported by the Original Disclosure is in Error, the

Examiner's Decision to Reject These Claims Should be Reversed, and the

Application Should be Remanded to the Examiner.

Reversal of the rejection of claims 24, 25, 27, 32-36, 41, 42, 48-63, 74 and 75 under 35 USC 112, first paragraph, as containing subject matter which is not supported by the original disclosure is requested.

As was pointed out in the Interview of July 31, 2003, and as was apparently acknowledged by the Examiner, claims 22-75 recite features substantially similar to original claims 1-21 and which are fully supported by the original disclosure.

For example, claim 22 recites many of the features of original claim 1 and further recites the inner and outer zones. However, e.g., page 5, line 33 to page 6, line 12 provides clear support for the recited inner and outer zones.

Appellant also directs the Examiner's attention to the following:

Claim 24 finds clear support in original claim 2. Moreover, Figs. 4 and 5 provide clear support for the recited features.

Claims 25 and 27 find clear support in original claim 3. Moreover, Figs. 4 and 5 provide clear support for the recited features.

Claim 32 finds clear support in Figs. 4 and 5.

Claim 33 finds clear support in original claim 5. Moreover, Figs. 4 and 5 provide clear support for the recited features.

Claims 34 and 35 find clear support in original claim 6. Moreover, Figs. 4 and 5 provide clear support for the recited features.

Claim 36 finds clear support in Fig. 4.

Claims 41 and 42 find clear support in original claim 8. Moreover, Figs. 4 and 5 provide clear support for the recited features.

Claim 48 finds clear support in original claim 10. Moreover, Figs. 4 and 5 provide clear support for the recited features.

Claims 49-52 find clear support in original claims 11-12. Moreover, Figs. 4 and 5 provide clear support for the recited features.

Claims 53-54 find clear support in original claim 13. Moreover, Fig. 6 provides clear support for the recited features.

Claims 55-57 find clear support in original claim 14. Moreover, Fig. 6 provides clear support for the recited features.

Claim 58 finds clear support in Fig. 5.

Claims 59-60 find clear support in original claim 15. Moreover, Fig. 6 provides clear support for the recited features.

Claims 61-62 find clear support in original claim 16.

Claims 63 finds clear support in original claim 17. Moreover, Fig. 6 provides clear support for the recited features.

Claims 74 finds clear support in original claims 1 and 17. Moreover, Figs. 4 and 5 provide clear support for the recited features.

Claims 75 finds clear support in original claim 1, lines 1-13 of page 7, and Figs. 4-6.

With regard to the Examiner's assertion that Appellant has not provided a statement that the Amendment filed May 9, 2002 contains no new matter, Appellant is unaware of any such requirement when filing a preliminary amendment. However, Appellant is not adverse to asserting such a statement and hereby states that both the Drawing Amendment and the Preliminary Amendment filed May, 9, 2003 contain no new matter.

Appellant further submits that the Examiner has failed to point to a single feature that is not recited in the original claims and/or that is not fully supported by the original specification and drawings.

Finally, Appellant submits that one having ordinary skill in the art having read the specification and drawings would have no difficulty understanding the description of the invention as recited in the claims.

Finally, to the extent that the Examiner believes that some terms are not literally used in the original disclosure, Appellant reminds the Examiner that "the failure of the

specification to specifically mention a limitation that later appears in the claims is not a fatal one when one skilled in the art would recognize upon reading the specification that the new language reflects what the specification shows has been invented." See *All Dental Prodx*, *LLC v. Advantage Dental Products, Inc.*, 02-1107 (Fed. Cir. 2002) noting *Eiselstein v. Frank*, 52 F.3d 1035, 1039, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995). A copy of the *All Dental Prodx* case has already been provided to the Examiner.

Accordingly, Appellant submits that none of the claims contain new matter and all of the claims are fully supported by the original disclosure. Thus, for reasons given above, reversal is requested of the Examiner's decision to finally reject claims 24, 25, 27, 32-36, 41, 42, 48-63, 74 and 75 as not being supported in the original disclosure.

(3) The Rejection of Claims 22-75 Under 35 U.S.C. section 112, Second

Paragraph, as Being Indefinite is in Error, the Examiner's Decision to

Reject These Claims Should be Reversed, and the Application Should be

Remanded to the Examiner.

Reversal of the rejection of claims 22-75 under 35 USC 112, second paragraph, as being indefinite is requested.

The Examiner presented a number of assertions and suggestions in formulating the rejection. Appellant respectfully traverses this rejection and each and every assertion made

by the Examiner in this rejection.

As a preliminary matter, Appellant does not disagree that some limitations broadly encompass the invention. Nor does Appellant dispute that some of the Examiner's suggestions could be adopted without significantly narrowing the claims. However, this is beside the point.

Appellant is unaware of any requirement, under either the patent statutes or rules, requiring Appellant to rewrite the claims in a manner which would please the Examiner or to limit the invention to any particular or preferred disclosed embodiment. Appellant reminds the Examiner that if the claim limitations are clear and have support in the specification, they cannot be properly rejected as indefinite merely because the Examiner would prefer that the claims recite more detailed limitations.

Moreover, the Examiner has set forth no legal basis for requiring Appellant to limit the invention. Appellant submits that the requirement that the claims be interpreted in light of the specification provides sufficient basis for the definiteness of the claims. Finally, the Examiner is reminded that Appellant is entitled to the broadest reasonable interpretation permitted by the prior art, and that one of ordinary skill in the art, having read the specification, would understand what the claims define.

Appellant notes, for example, that claim 22 recites inner and outer zones. However, this language is clearly and fully described and shown in the specification and drawings.

Moreover, Appellant has demonstrated that this language or terminology is well known in the prior art. Appellant directs the Examiner to Fig. 2 (which is labeled Prior Art). There, it can be seen that the language referring to inner zones 25, 25 and outer zones 27, 28 is clearly understood by those of ordinary skill in the art.

Appellant also notes that the recitation of the "wherein" clause in the body of the claims serves to limit the claim preamble and is therefore not redundant.

Appellant additionally notes that there is no requirement, and the Examiner has identified none, that certain features, e.g., first, second, fourth and fifth distances, be specifically defined in the claims. Such features are shown in the drawings and described in the specification.

Appellant further notes that there is no requirement to fully describe an operative invention in the claims. Claims can be broadly written to encompass an invention, while the specification describes a fully operative invention.

Appellant additionally notes that a recitation in a dependent claim which positively recites a feature not positively recited in an independent claim (e.g., the filling material in claims 22 and 23) is perfectly acceptable under current USPTO rules. Clearly, the addition of the filling material in dependent claim 23 serves to further limit claim 22.

The other asserted bases are similarly improper and contrary to current USPTO policy in interpreting claims under 35 U.S.C. § 112, second paragraph.

Finally, Appellant makes the following general comments in response to the Examiner's numerous grounds of rejection under 35 U.S.C. § 112, second paragraph. *The breadth of a claim is not to be equated with indefiniteness.* As concerns the breath of a claim, the primary concern is the *scope* of the claim relative to the scope of enablement provided to one skilled in the art by the disclosure. Claims should not be rejected as unduly broad under 35 U.S.C. § 112, second paragraph, for non-inclusion of limitations dealing with factors which must be presumed within the level of one of ordinary skill in the art; the claims need not recite such factors where one of ordinary skill in the art to whom the specification and claims are directed would consider them obvious. *In re Skrivan*, 427 F.2d 801,166 USPQ 85 (C.C.P.A. 1970).

Moreover, Appellant submits that excessive 35 U.S.C. § 112, second paragraph rejections, should not be used as a substitute for prior art in an attempt to try to get Appellant to narrow the claims. Rather, 35 U.S.C. § 112, second paragraph rejections, should pertain to definiteness and clarity of the claims.

Furthermore, definiteness of claim language is always analyzed in light of the teachings of the prior art, the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art, and the level of skill of the artisan in that art (*In re Moore*, 439 F.2d 1232, 169 USPQ 236 (C.C.P.A. 1971). The essential question to be asked under 35 U.S.C. § 112, second paragraph, is whether the scope

of the invention sought to be patented can be determined from the language of the claims. If the answer is yes, then the claims should not be rejected as being indefinite based on the second paragraph of 35 U.S.C. § 112. In particular, claims should be analyzed to determine whether they define the invention with a reasonable degree of particularity, clarity, and distinctness. See Patent and Trademark Office, Office of Policy and Dissemination Training Materials on Special Topics, 35 U.S.C. § 112, Second Paragraph, provided by the U.S.P.T.O. Patent Academy to Examiners for training purposes (1998).

Thus, with respect to the above-noted formal rejection and each and every asserted basis of indefiniteness, Appellant traverses all grounds of the Examiner's rejection based on the notion that the Examiner is only attacking the <u>scope</u> of Appellant's claims, <u>not definiteness</u>. As mentioned above, the breadth of a claim is not to be equated with indefiniteness.

Needless to say, Appellant is of the opinion, that the Examiner has misapplied 35 U.S.C. § 112, second paragraph, to Appellant's claims. The Examiner has burdened Appellant with excessive grounds of rejections and questions which do not apply to clarity of the claims, but instead deal with the scope and breadth of the invention claimed.

Overall, the questions the Examiner presents are questions which can and should be easily answered by applying basic claim interpretation rules and also relying on the instant disclosure. Appellant respectfully refers the Examiner to review the specification so that the

questions he presents can be answered.

Accordingly, Appellant submits that, measured against the correct standard enunciated above, none of the claims are indefinite. Thus, for reasons given above, reversal of the Examiner's decision to finally reject claims 22-75 as indefinite is requested.

Anticipated, or in the Alternative, Under 35 U.S.C. section 102(b) as Being

Obvious Over GB 2 136 692 to SCHWEIKHART is in Error, the

Examiner's Decision to Reject This Claim Should be Reversed, and the

Application Should be Remanded to the Examiner.

Reversal of the rejection of claims 22-75 under 35 USC 102(b) as being anticipated by, or in the alternative, as obvious under 35 USC 103(a) as being obvious over GB 2 136 692 to SCHWEIKHART is requested.

In the rejection, the Examiner asserted that this document discloses all of the features of these claims including, among other things, a prosthesis which is specific to either the right or left side. Appellant respectfully disagrees.

As was pointed out in the Interview, this document fails to disclose or even suggest, inter alia, an implantable breast prosthesis which is specific to either a right breast side or a left breast side of a patient, mush less, one which comprises a soft pouch that is specific to

either the right breast side or the left breast side of the patient, as recited in independent claims 22, 74 and 75. It was specifically pointed out that SCHWEIKHART discloses a symmetrical implant which is clearly not side specific. This is born out by the drawings and by the disclosure in lines 75-76 which states that the original shape is restored even if the implant experiences deformation.

Appellant disagrees with the Examiner's comments in the Interview that the disclosed implant is side specific because it can be used on either breast side. Appellant notes that the implant of SCHWEIKHART can be used on either breast side. This is precisely the point. Exactly because the disclosed implant can be used on either side, renders it non-side specific.

Furthermore, the Examiner did recognize during the Interview that Appellant is claiming a prosthesis which is both <u>side specific</u> and which has the form of <u>a soft pouch</u> that is capable of being filled with a filling material. On the other hand, it is clear from the drawings that SCHWEIKHART discloses an implant that is formed from solid materials. Indeed, page 1, lines 68-70 clearly indicates that the body is "sufficiently rigid or dimensionally stable, such that it is not visibly deformed in any position under its own weight."

Thus, Appellant respectfully submits that this document clearly fails to disclose or suggest, inter alia, an implantable breast prosthesis which is specific to either a right breast side or a left breast side of a patient, and which comprises a soft pouch that is specific to

either the right breast side or the left breast side of the patient, as recited in independent claims 22, 74 and 75.

Appellant notes that this document is clearly directed to a temporary insert and clearly lacks any disclosure to a breast prosthesis (see lines 5-10 of page 1). Nor can it be said that this document discloses a soft pouch, much less, one that is specific to either the right breast side or the left breast side of the patient. Appellant reminds the Examiner that each and every claim recites a breast prosthesis including a soft pouch that is specific to either the right breast side or the left breast side. On the other hand, the device disclosed in SCHWEIKHART is disclosed as being a plastic body temporary insert that is "sufficiently rigid or dimensionally stable" (see lines 68-70 of page 1). It is also clear from Fig. 1 that the body is symmetrical and, therefore, clearly non-specific to either the right or left sides.

It is also noted that, contrary to the Examiner's assertions, the various recited zones and points are clearly not disclosed in this document. Moreover, Appellant submits that the Examiner has mis-characterized this document and the claims, and further, has simply disregarded most of the numerous features recited in the claims.

Appellant emphasizes that this document clearly lacks any disclosure with regard to an implantable breast prosthesis, much less, one that is specific to either a right breast side or a left breast side of a patient. Nor is the disclosed device a soft pouch, much less, one that is specific to either the right breast side or the left breast side of the patient. Contrary to the

Examiner's assertion, the disclosed plastic body is clearly not a breast prosthesis, not a soft pouch and not specific to either the right breast side or the left breast side of the patient.

Appellant additionally submits that the Examiner has set forth no legal basis for disregarding and/or for not giving patentable weight to the above-noted recited features. Appellant submits that the Examiner is not free to disregard features which describe and limit the invention. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1306, 51 USPQ2d 1161, 1166 (Fed. Cir. 1999).

Appellant notes that, for an anticipation rejection under 35 U.S.C. § 102 to be proper, each element of the claim in question must be disclosed in a single document, and if the document relied upon does not do so, then the rejection must be withdrawn.

Moreover, because the above-noted applied document fails to disclose or suggest at least the above-noted features of the instant invention, Appellant submits that no proper modification of this document can render unpatentable the combination of features recited in at least independent claims 22, 74 and 75.

Further, even assuming, *arguendo*, that it would have been obvious to modify SCHWEIKHART to include the missing features, (which Appellant submits it would not be), Appellant notes that the teachings of SCHWEIKHART would nevertheless fail to result in a device having the combination of features recited in at least claims 22, 74 and 75.

Furthermore, Appellant submits that there is no motivation or rationale disclosed or

suggested in the art to modify SCHWEIKHART in the manner asserted by the Examiner. Nor does the Examiner's opinion provide a proper basis for these features or for the motivation to modify this document in the manner suggested by the Examiner. Therefore, Appellant submits that the invention as recited in at least independent claims 22, 74 and 75 is not rendered obvious by any reasonable inspection and interpretation of SCHWEIKHART.

Finally, Appellant submits that claims 23-73 are allowable at least for the reason that these claims depend from an allowable base claim and because these claims further recite features which provide a separate base for patentability in that the recited features are not suggested by any modification of this document. In particular:

claim 23 stands or falls with claim 22;

claim 24 depends from claim 22 and further recites that the soft pouch is asymmetrical in relation to a plane which passes through an upper zone of the soft pouch, a nipple area of the soft pouch and a lower zone of the soft pouch, when the soft pouch is implanted in the patient and filled. The asymmetrical design and the plane P1 are shown in Fig. 4. On the other hand, the Examiner has identified no disclosure in SCHWEIKHART which specifically disclose these features. Moreover, Fig. 1 of SCHWEIKHART shows what appears to be a symmetrical prostheses. Finally, Appellant submits that absent Appellant's disclosure, there would be no reason to modify the symmetrical device of SCHWEIKHART into an asymmetrical device;

claim 25 depends from claim 24 and further recites that the asymmetry is defined by a difference in dimensions between a first distance and a second distance defined by a plane passing through the inner zone, the nipple area and the outer zone, whereby the plane passing through the inner zone, the nipple area and the outer zone is perpendicular to a plane passing through the upper zone, the nipple area and the lower zone. Again, this asymmetrical design is shown in Fig. 4. Additionally, the plane containing points A, E and C has first distance AE and second distance EC. On the other hand, the Examiner has identified no disclosure in SCHWEIKHART which specifically discloses these features. Moreover, Fig. 1 of SCHWEIKHART shows what appears to be symmetrical prostheses. Finally, Appellant submits that absent Appellant's disclosure, there would be no reason to modify the symmetrical device of SCHWEIKHART into an asymmetrical device;

claim 26 depends from claim 25 and further recites that the first distance is different from the second distance. This is shown in Fig. 4 wherein the plane containing points A, E and C has first distance AE and second distance EC which are different from each other. On the other hand, the Examiner has identified no disclosure in SCHWEIKHART which specifically discloses these features. Moreover, Fig. 1 of SCHWEIKHART shows what appears to be symmetrical prostheses which would have identical distances;

claim 27 stands or falls with claim 25;

claim 28 depends from claim 27 and further recites that a ratio r of the second distance

to the first distance is less than or equal to 0.95. Again, these distances are shown in Fig. 4 wherein the plane containing points A, E and C has first distance AE and second distance EC which are different from each other. On the other hand, the Examiner has identified no disclosure in SCHWEIKHART which specifically discloses these features. Moreover, Fig. 1 of SCHWEIKHART shows what appears to be <u>symmetrical</u> prostheses which would have identical distances;

claims 29-31 stand or fall with claim 28;

claim 32 depends from claim 25 and further recites that the soft pouch further comprises a rear outer zone adjacent the outer zone, and wherein the plane passes through the inner zone, the nipple area, the outer zone and the rear outer zone. The rear outer zone is shown in Fig. 5 in the area of plane P5 of anterior surface 52, i.e., the outer zone is defined between points A and k of surface 52. On the other hand, the Examiner has identified no disclosure in SCHWEIKHART which specifically disclose these features;

claim 33 stands or falls with claim 32;

claim 34 depends from claim 24 and further recites that the asymmetry is defined by a difference in dimensions between a fourth distance and a fifth distance defined by a plane passing through the upper zone, the nipple area and the lower zone, whereby the plane passing through the upper zone, the nipple area and the lower zone is perpendicular to a plane passing through the inner zone, the nipple area and the outer zone. The asymmetrical

design and the plane P1 and the plane passing through AEC are shown in Fig. 4.—On the other hand, the Examiner has identified no disclosure in SCHWEIKHART which specifically disclose these features. Moreover, Fig. 1 of SCHWEIKHART shows what appears to be symmetrical prostheses. Finally, Appellant submits that absent Appellant's disclosure, there would be no reason to modify the symmetrical device of SCHWEIKHART into an asymmetrical device;

claims 35-37 depend from claim 34 and further respectfully recite that the fourth distance is different from the fifth distance, that the fourth distance is defined between an edge of the upper zone and a point in the nipple area and wherein the fifth distance is defined between an edge of the lower zone and the point in the nipple area, and that the fourth distance is greater than the fifth distance. This is shown in Fig. 4 wherein the plane containing points B, E and D has fourth distance BE and fifth distance ED which are different from each other. On the other hand, the Examiner has identified no disclosure in SCHWEIKHART which specifically discloses these features. Moreover, Fig. 1 of SCHWEIKHART shows what appears to be symmetrical prostheses which would have identical distances;

claim 38 depends from claim 37 and further recites that a ratio r of the fourth distance to the fifth distance is at least 1.1. Again, these distances are shown in Fig. 4 wherein the plane containing points B, E and D has fourth distance BE and fifth distance ED which are

different from each other. On the other hand, the Examiner has identified no disclosure in SCHWEIKHART which specifically discloses these features. Moreover, Fig. 1 of SCHWEIKHART shows what appears to be <u>symmetrical</u> prostheses which would have identical distances;

claims 39 and 40 stand or fall with claim 38;

claim 41 depends from claim 22 and further recites that the soft pouch further comprises an outer overlap portion in an area of the outer zone, when the soft pouch is implanted in the patient and filled. The outer zone is shown in Fig. 5 in the area of plane P5 of anterior surface 52, i.e., the outer zone is defined between points A and k of surface 52. On the other hand, SCHWEIKHART clearly lacks such an outer zone. Moreover, the Examiner has identified no disclosure in SCHWEIKHART which specifically discloses this feature;

claim 42 depends from claim 41 and further recites that the outer overlap portion extends to each of the upper zone and the lower zone. Again, the outer zone is shown in Fig. 5 in the area of plane P5 of anterior surface 52, i.e., the outer zone is defined between points A and k of surface 52. On the other hand, SCHWEIKHART clearly lacks such an outer zone. Moreover, the Examiner has identified no disclosure in SCHWEIKHART which specifically discloses this feature;

claim 43 depends from claim 42 and further recites that the angle ϕ is greater than 95

degrees. Again, the outer zone is shown in Fig. 5 in the area of plane P5 of anterior surface 52 and the recited angle is also defined by planes P5 and P6 which intersect at point k. On the other hand, the Examiner has identified no disclosure in SCHWEIKHART which specifically discloses this feature;

claims 44 and 45 stand or fall with claim 43;

claims 46 and 47 stand or fall with claim 41;

claim 51 depends from claim 48 and further recites that a distance between a plane extending through an edge of the inner zone and an edge of the outer zone and a parallel plane extending through a point on the posterior surface that is furthest away from the plane extending through the edge of the inner zone and the edge of the outer zone is at least 5 mm. Fig. 5 shows the plane kG'C spaced and parallel from the plane AG. While Fig. 3 of SCHWEIKHART shows a curved posterior surface between what appears to be inner and outer zones, it nevertheless lacks any disclosure to the recited distance;

claim 52 depends from claim 48 and further recites that a distance between a plane extending through an edge of the inner zone and an edge of the outer zone and a parallel plane extending through a point on the posterior surface that is farthest away from the plane extending through the edge of the inner zone and the edge of the outer zone is at least 1 cm. Again, Fig. 5 shows the plane kG'C spaced and parallel from the plane AG. While Fig. 3 of SCHWEIKHART shows a curved posterior surface between what appears to be inner and

outer zones, it nevertheless lacks any disclosure to the recited distance;

claim 53 depends from claim 48 and further recites that the posterior surface is at least one of concave and curved between an edge of an upper zone and an edge of a lower zone. Fig. 5 shows the curved or concave posterior surface 51 between upper zone C and lower zone k. On the other hand, Fig. 2 of SCHWEIKHART shows a flat posterior surface between what appears to be the upper and lower zones;

claim 54 depends from claim 48 and further recites that the posterior surface is at least one of concave and curved at least in an area of an upper zone. Again, Fig. 5 shows the curved or concave posterior surface 51 in the upper zone between points G and C. On the other hand, Fig. 2 of SCHWEIKHART shows a flat posterior surface between what appears to be the upper and lower zones;

claim 55 depends from claim 48 and further recites that a distance between a plane extending through an edge of an upper zone and an edge of a lower zone and a parallel plane extending through a point on the posterior surface that is furthest away from the plane extending through the edge of the upper zone and the edge of the lower zone is at least 1 mm. This feature is shown in Fig. 6 which illustrates the recited distance between points H and H'. On the other hand, Fig. 2 of SCHWEIKHART shows a flat posterior surface between what appears to be the upper and lower zones;

claim 56 depends from claim 48 and further recites that a distance between a plane

extending through an edge of an upper zone and an edge of a lower zone and a parallel plane extending through a point on the posterior surface that is furthest away from the plane extending through the edge of the upper zone and the edge of the lower zone is at least 2 mm. This feature is shown in Fig. 6 which illustrates the recited distance between points H and H'. On the other hand, Fig. 2 of SCHWEIKHART shows a flat posterior surface between what appears to be the upper and lower zones;

claim 57 depends from claim 48 and further recites that a distance between a plane extending through an edge of an upper zone and an edge of a lower zone and a parallel plane extending through a point on the posterior surface that is furthest away from the plane extending through the edge of the upper zone and the edge of the lower zone is in the range of between 3 mm and 6 mm. This feature is shown in Fig. 6 which illustrates the recited distance between points H and H'. On the other hand, Fig. 2 of SCHWEIKHART shows a flat posterior surface between what appears to be the upper and lower zones;

claims 58 stands or falls with claim 22;

claim 59 depends from claim 58 and further recites that a distance between a plane extending through an edge of an upper zone and an edge of a lower zone and a parallel plane extending through a point on the anterior surface that is furthest away from the plane extending through the edge of the upper zone and the edge of the lower zone is in the range of between 3 cm and 7 cm. This feature is shown in Fig. 6 which illustrates the recited

distance between points H' and I. While Fig. 2 of SCHWEIKHART shows that the pole of the curved anterior surface is spaced from the flat posterior surface by some distance, it nevertheless lacks any disclosure to the recited distance;

claim 60 depends from claim 58 and further recites that a distance between a plane extending through an edge of an upper zone and an edge of a lower zone and a parallel plane extending through a point on the anterior surface that is furthest away from the plane extending through the edge of the upper zone and the edge of the lower zone is on the order of 5 cm. This feature is shown in Fig. 6 which illustrates the recited distance between points H' and I. Again, while Fig. 2 of SCHWEIKHART shows that the pole of the curved anterior surface is spaced from the flat posterior surface by some distance, it nevertheless lacks any disclosure to the recited distance;

claim 61 depends from claim 22 and further recites that at least a portion of the posterior surface is one of less deformable and more rigid than another portion of the soft pouch. This feature is described on lines 22-24 of page 4. On the other hand, the Examiner has identified no disclosure in SCHWEIKHART which specifically discloses this feature;

claim 62 depends from claim 61 and further recites that the portion of the posterior surface that is one of less deformable and more rigid than another portion of the soft pouch has a thicker surface than the other portion of the soft pouch. Again, this feature is described in lines 22-24 of page 4. On the other hand, the Examiner has identified no disclosure in

SCHWEIKHART which specifically discloses this feature;

Claims 63-69 stand or fall with claim 22;

claims 70 and 71 depend from claim 22 and further respectively recite that the soft pouch comprises an elastomer and that the elastomer comprises silicone. This feature is described in original claim 19. On the other hand, SCHWEIKHART merely discloses a rigid body made of acrylic glass (see page 1, lines 69-71 and claims 2 and 6);

claim 72 depends from claim 22 and further recites that the soft pouch is adapted to be filled with the filling material either before or after being implanted into the patient. This feature is described in original claim 20. On the other hand, SCHWEIKHART merely discloses a rigid body which may be made hollow (see page 1, lines 69-71, Fig. 4, and page 2, lines 27-34); and

claim 73 depends from claim 22 and further recites that the implantable breast prosthesis comprises an expansion prosthesis. This feature is described in original claim 21. Again, SCHWEIKHART merely discloses a rigid body which may be made hollow (see page 1, lines 69-71, Fig. 4, and page 2, lines 27-34).

Thus, for reasons given above, reversal of the Examiner's decision to finally reject claims 22-75 is requested. Further, Appellant requests that the application be remanded to the Examiner for allowance.

I. CONCLUSION

For the reasons advanced above, Appellant submits that the objections and rejections are erroneous and that the Examiner's decision to reject claims 22-75 should be reversed. Claims 24, 25, 27, 32-36, 41, 42, 48-63, 74 and 75 are fully supported by the original disclosure, claims 22-75 are not indefinite, and claims 22-75 patentably define over the applied art of record.

This appeal brief is being submitted in triplicate, pursuant to 37 CFR 1.192(a).

A check is enclosed in the amount of \$165.00 for payment of the fee for filing an appeal brief, as set forth in 37 CFR 1.17(c).

The Commissioner is authorized to charge any additional fee, or to credit any overpayment, to Deposit Account No. 19-0089.

Respectfully submitted, Marie-Christine MISSANA

RG. NO. 45, 29.

Neil F. Greenblum Reg. No. 28,394

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Attachment: Appendix

APPENDIX

Claims on appeal:

22. An implantable breast prosthesis which is specific to either a right breast side or a left breast side of a patient, the prosthesis comprising:

a soft pouch adapted to contain a filling material;

the soft pouch comprising a posterior surface, an anterior surface, an inner zone and an outer zone; and

the posterior surface and the anterior surface forming an angle β in the inner zone of less than 70 degrees when the soft pouch is implanted and filled with the filling material,

wherein the soft pouch is specific to either the right breast side or the left breast side of the patient.

- 23. The prosthesis claim 22, wherein the filling material comprises one of a silicone gel and a physiological serum.
- 24. The prosthesis of claim 22, wherein the soft pouch is asymmetrical in relation to a plane which passes through an upper zone of the soft pouch, a nipple area of the soft pouch and a lower zone of the soft pouch, when the soft pouch is implanted in the patient and filled.
- 25. The prosthesis of claim 24, wherein the asymmetry is defined by a difference in dimensions between a first distance and a second distance defined by a plane passing through the inner zone, the nipple area and the outer zone, whereby the plane passing through the inner zone, the nipple area and the outer zone is perpendicular to a plane passing through the upper zone, the nipple area and the lower zone.
- 26. The prosthesis of claim 25, wherein the first distance is different from the second distance.

- 27. The prosthesis of claim 25, wherein the first distance is defined between an edge of the inner zone and a point in the nipple area and wherein the second distance is defined between an edge of the outer zone and the point in the nipple area.
- 28. The prosthesis of claim 27, wherein a ratio r of the second distance to the first distance is less than or equal to 0.95.
- 29. The prosthesis of claim 28, wherein the ratio r is in the range of between 0.8 and 0.9.
- 30. The prosthesis of claim 29, wherein the ratio r is in the range of between 0.85 and 0.9.
 - 31. The prosthesis of claim 30, wherein the ratio r is about 0.875.
- 32. The prosthesis of claim 25, wherein the soft pouch further comprises a rear outer zone adjacent the outer zone, and wherein the plane passes through the inner zone, the nipple area, the outer zone and the rear outer zone.
- 33. The prosthesis of claim 32, further comprising a third distance being defined between an edge of the rear outer zone and a point in the nipple area, whereby the first distance is defined between the point in the nipple area and an edge of the inner zone, the first distance and the third distance being at least one of equal to each other and very close to each other.
- 34. The prosthesis of claim 24, wherein the asymmetry is defined by a difference in dimensions between a fourth distance and a fifth distance defined by a plane passing through the upper zone, the nipple area and the lower zone, whereby the plane passing through the

upper zone, the nipple area and the lower zone is perpendicular to a plane passing through the inner zone, the nipple area and the outer zone.

- 35. The prosthesis of claim 34, wherein the fourth distance is different from the fifth distance.
- 36. The prosthesis of claim 34, wherein the fourth distance is defined between an edge of the upper zone and a point in the nipple area and wherein the fifth distance is defined between an edge of the lower zone and the point in the nipple area.
- 37. The prosthesis of claim 36, wherein the fourth distance is greater than the fifth distance.
- 38. The prosthesis of claim 37, wherein a ratio r of the fourth distance to the fifth distance is at least 1.1.
- 39. The prosthesis of claim 38, wherein the ratio r is in the range of between 1.1 and 2.
- 40. The prosthesis of claim 39, wherein the ratio r is in the range of between 1.3 and 1.5.
- 41. The prosthesis of claim 22, wherein the soft pouch further comprises an outer overlap portion in an area of the outer zone, when the soft pouch is implanted in the patient and filled.
- 42. The prosthesis of claim 41, wherein the outer overlap portion extends to each of the upper zone and the lower zone.

- 43. The prosthesis of claim 41, wherein the outer overlap portion comprises an anterior surface which forms an obtuse angle ϕ relative to the posterior surface.
 - 44. The prosthesis of claim 43, wherein the angle ϕ is greater than 95 degrees.
 - 45. The prosthesis of claim 44, wherein the angle ϕ is greater than 100 degrees.
- 46. The prosthesis of claim 41, wherein the angle ϕ is in the range of between 91 degrees and 120 degrees.
 - 47. The prosthesis of claim 46, wherein the angle ϕ is 115 degrees.
- 48. The prosthesis of claim 22, wherein the posterior surface is at least one of concave and curved.
- 49. The prosthesis of claim 48, wherein the posterior surface is at least one of concave and curved between an edge of the inner zone and an edge of the outer zone.
- 50. The prosthesis of claim 48, wherein the posterior surface is at least one of concave and curved at least in an area of the inner zone.
- 51. The prosthesis of claim 48, wherein a distance between a plane extending through an edge of the inner zone and an edge of the outer zone and a parallel plane extending through a point on the posterior surface that is farthest away from the plane extending through the edge of the inner zone and the edge of the outer zone is at least 5 mm.
- 52. The prosthesis of claim 48, wherein a distance between a plane extending through an edge of the inner zone and an edge of the outer zone and a parallel plane extending

through a point on the posterior surface that is farthest away from the plane extending through the edge of the inner zone and the edge of the outer zone is at least 1 cm.

- 53. The prosthesis of claim 48, wherein the posterior surface is at least one of concave and curved between an edge of an upper zone and an edge of a lower zone.
- 54. The prosthesis of claim 48, wherein the posterior surface is at least one of concave and curved at least in an area of an upper zone.
- 55. The prosthesis of claim 48, wherein a distance between a plane extending through an edge of an upper zone and an edge of a lower zone and a parallel plane extending through a point on the posterior surface that is farthest away from the plane extending through the edge of the upper zone and the edge of the lower zone is at least 1 mm.
- 56. The prosthesis of claim 48, wherein a distance between a plane extending through an edge of an upper zone and an edge of a lower zone and a parallel plane extending through a point on the posterior surface that is farthest away from the plane extending through the edge of the upper zone and the edge of the lower zone is at least 2 mm.
- 57. The prosthesis of claim 48, wherein a distance between a plane extending through an edge of an upper zone and an edge of a lower zone and a parallel plane extending through a point on the posterior surface that is farthest away from the plane extending through the edge of the upper zone and the edge of the lower zone is in the range of between 3 mm and 6 mm.
- 58. The prosthesis of claim 22, wherein the anterior surface is at least one of curved and convex.

- 59. The prosthesis of claim 58, wherein a distance between a plane extending through an edge of an upper zone and an edge of a lower zone and a parallel plane extending through a point on the anterior surface that is farthest away from the plane extending through the edge of the upper zone and the edge of the lower zone is in the range of between 3 cm and 7 cm.
- 60. The prosthesis of claim 58, wherein a distance between a plane extending through an edge of an upper zone and an edge of a lower zone and a parallel plane extending through a point on the anterior surface that is farthest away from the plane extending through the edge of the upper zone and the edge of the lower zone is on the order of 5 cm.
- 61. The prosthesis of claim 22, wherein at least a portion of the posterior surface is one of less deformable and more rigid than another portion of the soft pouch.
- 62. The prosthesis of claim 61, wherein the portion of the posterior surface that is one of less deformable and more rigid than another portion of the soft pouch has a thicker surface than the other portion of the soft pouch.
- 63. The prosthesis of claim 22, wherein the posterior surface and the anterior surface form an angle δ in an upper zone of less than 70 degrees when the soft pouch is implanted and filled with the filling material.
 - 64. The prosthesis of claim 63, wherein the angle δ is less than 65 degrees.
 - 65. The prosthesis of claim 64, wherein the angle δ is less than 60 degrees.
 - 66. The prosthesis of claim 65, wherein the angle δ is about 40 degrees.
 - 67. The prosthesis of claim 22, wherein the angle β is less than 65 degrees.

- 68. The prosthesis of claim 67, wherein the angle β is less than 60 degrees.
- 69. The prosthesis of claim 68, wherein the angle β is about 40 degrees.
- 70. The prosthesis of claim 22, wherein the soft pouch comprises an elastomer.
- 71. The prosthesis of claim 70, wherein the elastomer comprises silicone.
- 72. The prosthesis of claim 22, wherein the soft pouch is adapted to be filled with the filling material either before or after being implanted into the patient.
- 73. The prosthesis of claim 22, wherein the implantable breast prosthesis comprises an expansion prosthesis.
- 74. An implantable breast prosthesis which is specific to either a right breast side or a left breast side of a patient, the prosthesis comprising:

a soft pouch adapted to contain a filling material;

the soft pouch comprising a concave posterior surface, a convex anterior surface, an inner zone, an outer zone, an upper zone and a lower zone;

the posterior surface and the anterior surface forming an angle β in the inner zone of less than 70 degrees when the soft pouch is implanted and filled with the filling material; and

the posterior surface and the anterior surface forming an angle δ in the upper zone of less than 70 degrees when the soft pouch is implanted and filled with the filling material.

wherein the soft pouch is specific to either the right breast side or the left breast side of the patient.

75. An implantable breast prosthesis which is specific to either a right breast side or a left breast side of a patient, the prosthesis comprising:

a soft pouch adapted to contain a filling material;

the soft pouch comprising a concave posterior surface, a convex anterior surface, an inner zone, an outer zone, an upper zone and a lower zone;

the posterior surface and the anterior surface forming an angle β in the inner zone of less than 70 degrees when the soft pouch is implanted and filled with the filling material;

the posterior surface and the anterior surface forming an angle δ in the upper zone of less than 70 degrees when the soft pouch is implanted and filled with the filling material:

a nipple pole zone being defined on each of the posterior surface and the anterior surface;

an axis being defined by a line passing through a point on each of the nipple zones of the posterior surface and the anterior surface, whereby the axis is perpendicular to a plane which extends from an edge of the inner zone to an edge of the outer zone;

an upper outer part of the soft pouch being defined by a first plane extending through the upper zone and the lower zone, a second plane extending through the inner zone and the outer zone, an upper outer portion of the posterior surface and an upper outer portion of the anterior surface, whereby each of the first and second planes are perpendicular to each other;

an upper inner part of the soft pouch being defined by the first plane, the second plane, an upper inner portion of the posterior surface and an upper inner portion of the anterior surface;

a lower outer part of the soft pouch being defined by the first plane, the second plane, a lower outer portion of the posterior surface and a lower outer portion of the anterior surface; and

a lower inner part of the soft pouch being defined by the first plane, the second plane, a lower inner portion of the posterior surface and a lower inner portion of the anterior surface,

wherein each of the upper outer part, the upper inner part, the lower outer part and the lower inner part have different volumes, and

wherein the soft pouch is specific to either the right breast side or the left breast side

P21742.A12 of the patient.

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